



K131527

GE Healthcare  
510(k) Premarket Notification Submission

**510(k) Summary**

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: May 24, 2013

Submitter: GE Healthcare  
9900 Innovation Dr  
Wauwatosa, WI 53226

Manufacturer: GE Ultrasound Korea, Ltd.  
65-1 Sangdaewon-Dong, Jungwon-Gu  
Seongnam-Si, Gyeonggi-Do, Korea 462-120

Primary Contact Person: Bryan Behn  
Regulatory Affairs Manager  
GE Healthcare  
T:(414)721-4214  
F:(414)918-8275

Alternate Contact Person: Seiji Oikawa  
Regulatory Affairs Specialist  
GE Healthcare Japan Corporation  
T: +81-42-585-5123  
F: +81-42-585-5950

Device: Trade Name: LOGIQ S8 Ultrasound System

Common/Usual Name: LOGIQ S8

Classification Names: Class II

Product Code: Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN  
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO  
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Predicate Device(s): K111582 LOGIQ S8 Diagnostic Ultrasound System  
K123564 LOGIQ E9 Diagnostic Ultrasound System  
K122114 LOGIQ S7 Diagnostic Ultrasound System  
K113690 LOGIQ e Diagnostic Ultrasound System  
K101149 Vivid E9 Diagnostic Ultrasound System

AUG 26 2013



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Device Description: The LOGIQ S8 is a full featured, general purpose diagnostic ultrasound system which consists of a mobile console approximately 62 cm wide, 88 cm deep and 175 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 9-inch LCD touch screen and color 19-inch LCD image display.

Device Modifications: The following is an overview of the differences between the proposed LOGIQ S8 and the predicate LOGIQ S8 (K111582). The proposed LOGIQ S8 has had several features and probes migrated to it currently cleared on other GE Ultrasound systems.

The following features have been migrated from the LOGIQ E9 (K123564): 4D, Transesophageal application, Measure Assistant Breast, Measure Assistant OB, Compare Assistant, Breast and Thyroid Productivity Packages, Speed of Sound, VNAV Needle Tracking. The following probes have been migrated from the LOGIQ E9 (K123564): C2-9-D, 11L-D, 6S-D, S1-5-D, RAB6-D and RIC5-9-D.

The following features and probes have been migrated from the LOGIQ S7 (K122114): BSteer+ and the 3Sp-D probe.

The following features and probes have been migrated from the Vivid E9 (K101149): Auto EF

The following are new features and probes added in this submission: Auto Sweep and the C2-6b-D and 10C-D probes.

Intended Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, and vascular).



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Technology: The LOGIQ S8 employs the same fundamental scientific technology as its predicate devices

Determination of Substantial Equivalence: Summary of Non-Clinical Tests:  
The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The LOGIQ S8 and its applications comply with voluntary standards:

1. AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
2. IEC60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
7. ISO14971, Application of risk management to medical devices
8. NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)



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- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ S8, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ S8 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

August 26, 2013

BRYAN BEHN  
REGULATORY AFFAIRS MANAGER  
GE HEALTHCARE  
9900 INNOVATION DR.  
WAUWATOSA WI 53226

Re: K131527

Trade/Device Name: LOGIQ S8  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: May 24, 2013  
Received: May 28, 2013

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the LOGIQ S8 Ultrasound System, as described in your premarket notification:

Transducer Model Number

C1-5-D	9L-D	ML6-15-D
M5S-D	IC5-9-D	3CRF-D
L8-18i-D	S4-10-D	P2D
P6D	C2-9-D	11L-D
6S-D	S1-5-D	RAB6-D
RIC5-9-D	6Tc-RS	3Sp-D
C2-6b-D	10C-D	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number ~~(800)-638-2041 or (301)-796-7100 or at its Internet address~~ <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine Morris  
Director, Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure



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510(k) Number (if known): K131527

Device Name: LOGIQ S8

Indications for Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular and neurosurgical).

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

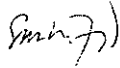
AND/OR

Over-The-Counter Use   NA    
(Part 21 CFR 801 Subpart C)

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IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



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(Division Sign-Off)  
Division of Radiological Health  
Office of *In Vitro* Diagnostics and Radiological Health

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### *Indications for Use Forms*

The following forms represent indications with clinical applications and exam types along with the modes of operation for the LOGIQ S8 system. Combinations identified "P" for the transducers represents those previously cleared on LOGIQ S8 or another GE Ultrasound system. Combinations identified "E" for the transducers represents those that have been added to the LOGIQ S8 under Appendix E of "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers Document issued on: September 9, 2008". Combinations identified "N" for the transducers represents those that are new. Please see section 11 Table 11.2.1 for information on previous clearance information on these transducers.

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**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ S8 Ultrasound System**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										Other [Notes]
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	5,6,9
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Pediatric	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Small Organ <sup>[2]</sup>	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	5,6,9
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	5,6,9
Cardiac	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Superficial	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	P	3,5,6,9
<i>Exam Type, Means of Access</i>											
Transesophageal	N	N	N	N	N	N	N	N	N	N	
Transrectal <sup>[8]</sup>	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Transvaginal	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Transurethral											
Intraoperative <sup>[6]</sup>	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Intraoperative Neurological	P	P	P	P	P	P	P	P	P	P	
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA;

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



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**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ S8 with C1-5-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										Other (Notes)
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	5,6,9
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Pediatric	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P	P	P	P	P	P	P	P	3,5,6,9
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>											
Transvaginal											
Transurethral											
Intraoperative <sup>[9]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

- Notes:
- [1] Abdominal includes Renal, GYN/Pelvic.
  - [2] Small organ includes breast, testes and thyroid
  - [3] Elastography Imaging - Elasticity.
  - [4] Other use includes Urology/Prostate
  - [5] 3D Imaging mode
  - [6] Needle guidance imaging
  - [7] Includes infertility monitoring of follicle development
  - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
  - [9] Volume navigation
  - [\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



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**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ S8 with 9L-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P		5,6,9
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	3,5,6,9
Pediatric	P	P	P		P	P	P	P	P	P	3,5,6,9
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	3,5,6,9
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	3,5,6,9
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>											
Transvaginal											
Transurethral											
Intraoperative <sup>[9]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)



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**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ S8 with ML6-15-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	P	P	P		P	P	P	P	P	P	3,5,6,9
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	3,5,6,9
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	9
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	3,5,6,9
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)



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**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ S8 with M5S-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	5,6,9
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	5,6,9
Pediatric	P	P	P	P	P	P	P	P	P	P	5,6,9
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	9
Cardiac	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>											
Transvaginal											
Transurethral											
Intraoperative <sup>[6]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ S8 with IC5-9-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	5,6,9
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P		P	P	P	P	P	P	3,5,6,9
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>	P	P	P		P	P	P	P	P	P	3,5,6,9
Transvaginal	P	P	P		P	P	P	P	P	P	3,5,6,9
Transurethral											
Intraoperative <sup>[9]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

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[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ S8 with 3CRF-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										Other [Notes]
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	5,6,9
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	5,6,9
Pediatric	P	P	P		P	P	P	P	P	P	5,6,9
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P	P	P		P	P	P	P	P	P	5,6,9
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[6]</sup>											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD. B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ S8 with L8-18i-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	3,5,6,9
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	3,5,6,9
Pediatric	P	P	P		P	P	P	P	P	P	5,6,9
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	3,5,6,9
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	3,5,6,9
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>	P	P	P		P	P	P	P	P	P	3,5,6,9
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ S8 with S4-10-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										Other (Notes)
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P	P	P	P	P	P	P	P	5,6,9
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	5,6,9
Pediatric	P	P	P	P	P	P	P	P	P	P	5,6,9
Small Organ <sup>[2]</sup>	P	P	P	P	P	P	P	P	P	P	5,6,9
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	5,6,9
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[6]</sup>											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ S8 with P2D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic			P	P							
Cardiac			P	P							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[6]</sup>											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



GE Healthcare  
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**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ S8 with P6D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other {Notes}
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic			P	P							
Cardiac			P	P							
Peripheral Vascular			P	P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>											
Transvaginal											
Transurethral											
Intraoperative <sup>[6]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ S8 with C2-9-D Transducer**

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other [Notes]
Anatomy/Region of Interest											
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Abdominal <sup>[1]</sup>	E	E	E	E	E	E	E	E	E	E	[3,5,6,9]
Pediatric	E	E	E	E	E	E	E	E	E	E	[3,5,6,9]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	E	E	E	E	E	E	E	E	E	E	[3,5,6,9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	E	E	E	E	E	E	E	E	E	E	[3,5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E (previously cleared K123564)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D/4D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ S8 with 11L-D Transducer**

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other (Notes)
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>	E	E	E		E	E	E	E	E	E	[3,5,6]
Pediatric	E	E	E		E	E	E	E	E	E	[3,5,6]
Small Organ <sup>[2]</sup>	E	E	E		E	E	E	E	E	E	[3,5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	E	E	E		E	E	E	E	E	E	[3,5,6]
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E	E	[3,5,6]
Musculo-skeletal Superficial	E	E	E		E	E	E	E	E	E	[3,5,6]
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[5]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E (previously cleared K123564)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D/4D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ S8 with 6S-D Transducer**

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse*	Other [Notes]
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	E	E	E	E	E	E	E	E	E	E	
Abdominal <sup>[1]</sup>	E	E	E	E	E	E	E	E	E	E	
Pediatric	E	E	E	E	E	E	E	E	E	E	
Small Organ <sup>[2]</sup>											
Neonatal Cephalic	E	E	E	E	E	E	E	E	E	E	
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric	E	E	E	E	E	E	E	E	E	E	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E (previously cleared K123564)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D/4D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ S8 with S1-5-D Transducer**

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other [Notes]
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Abdominal <sup>[1]</sup>	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Pediatric	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Cardiac Adult	E	E	E	E	E	E	E	E	E	E	
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E (previously cleared K123564)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D/4D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ S8 with RAB6-D Transducer**

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other [Notes]
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P*	P*	P*		P*	P*	P*	P*	P*	P*	[5,6]
Abdominal <sup>[1]</sup>	P*	P*	P*		P*	P*	P*	P*	P*	P*	[5,6]
Pediatric	P*	P*	P*		P*	P*	P*	P*	P*	P*	[5,6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional	P*	P*	P*		P*	P*	P*	P*	P*	P*	[5,6]
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P\* = previously cleared by FDA (previously cleared K123564)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D/4D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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GE Healthcare  
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**Diagnostic Ultrasound Indications for Use Form**  
**GE LOGIQ S8 with RIC5-9-D Transducer**

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other (Notes)
Ophthalmic											
Fetal/Obstetrics <sup>[7]</sup>	P*	P*	P*	P*	P*	P*	P*	P*	P*	P*	[5,6]
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>	P*	P*	P*	P*	P*	P*	P*	P*	P*	P*	[3,5,6]
Exam Type, Means of Access											
Transesophageal											
Transrectal	P*	P*	P*	P*	P*	P*	P*	P*	P*	P*	[3,5,6]
Transvaginal	P*	P*	P*	P*	P*	P*	P*	P*	P*	P*	[3,5,6]
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P\* = previously cleared by FDA (previously cleared K123564)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D/4D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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GE Healthcare  
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Diagnostic Ultrasound Indications for Use Form  
**GE LOGIQ S8 with 6Tc-RS Transducer**

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other [Notes]
Ophthalmic											
Fetal/Obstetrics <sup>[2]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult	P*	P*	P*	P*	P*	P*	P*	P*	P*	P*	
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal	P*	P*	P*	P*	P*	P*	P*	P*	P*	P*	
Transrectal											
Transvaginal											
Transurethral											
Intraoperative <sup>[6]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (\*previously cleared K113690)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D/4D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



**GE Healthcare**  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ S8 with 3Sp-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P*	P*	P*	P*	P*	P*	P*	P*	P*	P*	5,6
Abdominal <sup>[1]</sup>	P*	P*	P*	P*	P*	P*	P*	P*	P*	P*	5,6
Pediatric	P*	P*	P*	P*	P*	P*	P*	P*	P*	P*	5,6
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic	P*	P*	P*	P*	P*	P*	P*	P*	P*	P*	
Cardiac Adult & Pediatric	P*	P*	P*	P*	P*	P*	P*	P*	P*	P*	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[6]</sup>											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (previously cleared K122114)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D/4D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ S8 with C2-6b-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>	N	N	N		N		N	N	N	N	5,6,9
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>											
Transvaginal											
Transurethral											
Intraoperative <sup>[6]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA;

- Notes: [1] Abdominal includes Renal, GYN/Pelvic.  
 [2] Small organ includes breast, testes and thyroid  
 [3] Elastography Imaging - Elasticity.  
 [4] Other use includes Urology/Prostate  
 [5] 3D/4D Imaging mode  
 [6] Needle guidance imaging  
 [7] Includes infertility monitoring of follicle development  
 [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)  
 [9] Volume navigation  
 [\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.  
 System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)  
 Prescription User (Per 21 CFR 801.109)



GE Healthcare  
510(k) Premarket Notification Submission

**Diagnostic Ultrasound Indications for Use Form**

**GE LOGIQ S8 with 10C-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[1]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	N	N	N		N		N	N	N	N	5,6
Small Organ <sup>[2]</sup>											
Neonatal Cephalic	N	N	N		N		N	N	N	N	5,6
Adult Cephalic											
Cardiac Adult & Pediatric	N	N	N		N		N	N	N	N	5,6
Peripheral Vascular	N	N	N		N		N	N	N	N	5,6
Musculo-skeletal Conventional	N	N	N		N		N	N	N	N	5,6
Musculo-skeletal Superficial	N	N	N		N		N	N	N	N	5,6
Other <sup>[4]</sup>											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>											
Transvaginal											
Transurethral											
Intraoperative <sup>[8]</sup>											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA;

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

[2] Small organ includes breast, testes and thyroid

[3] Elastography Imaging - Elasticity.

[4] Other use includes Urology/Prostate

[5] 3D/4D Imaging mode

[6] Needle guidance imaging

[7] Includes infertility monitoring of follicle development

[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)

[9] Volume navigation

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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